Filing Date: November 3, 2003

Title: MULTI-SITE VENTRICULAR PACING THERAPY WITH PARASYMPATHETIC STIMULATION

REMARKS

This responds to the Office Action dated May 3, 2007.

Claims 1 and 11 are amended. Claims 1-20 are now pending in this application.

§112 Rejection of the Claims

Claims 1 and 11 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The rejections are traversed.

The office action contends that the simultaneous delivery of atrial and multi-site ventricular pacing in conjunction with parasympathetic stimulation is unsupported the specification. Applicant disagrees. At numerous places in the specification, the delivery of parasympathetic stimulation in conjunction with multi-site ventricular stimulation (i.e., ventricular resynchronization pacing) is discussed. The specification describes an exemplary device for implementing such pacing and parasympathetic stimulation and specifically states that the device's "multiple sensing/pacing channels may be configured, for example, with one atrial and two ventricular sensing/stimulation channels for delivering biventricular resynchronization therapy, with the atrial sensing/pacing channel used to deliver biventricular resynchronization therapy in an atrial tracking mode as well as to pace the atria if required." (pg. 8, lines 4-8) The specification also describes the delivery of ventricular resynchronization therapy in conjunction with a bradycardia pacing mode. (e.g., pg. 10, line 28-pg. 11, line 3) Applicant believes the term bradycardia mode when applied to ventricular pacing is understood to those of ordinary skill in the art to encompass both ventricle-only pacing modes (e.g., VVI and VDD) as well as combined atrial and ventricular pacing modes (e.g., DDD). Applicant has elected to amend claims 1 and 11 herein, however, in a manner that makes the issue moot. Claims 1 and 11 now a recite a device and method in which pacing pulses are delivered to multiple ventricular sites in accordance with a demand pacing mode that prevents slowing of the heart rate due to the parasympathetic stimulation, which limitation is discussed in the specification as one means by which the tendency of parasympathetic stimulation to decrease cardiac output may be counteracted. (pg. 6, lines 17-19) Such a demand pacing mode could, for example, be either a DDD or a VVI pacing mode.

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§102 and §103 Rejection of the Claims

Claims 1, 2, 4, 5, 7 and 8 were rejected under 35 U.S.C. § 102(e) as being anticipated by Adams et al. (U.S. 2003/0229380). Claims 1, 2, 4, 5, 7, 8, 10-12, 14, 15, 17, 18 and 20 were rejected under 35 U.S.C. § 102(e) as being anticipated by Casavant et al. (U.S. 2004/0088015). Claims 1-3, 5, 7, 8, 10-13, 15, 17, 18 and 20 were rejected under 35 U.S.C. § 102(e) as being anticipated by Shafer et al. (U.S. 2004/0172075). Claims 11, 12, 14, 15, 17 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Adams et al. (U.S. 2003/0229380). Claims 3, 6, 9, 10, 13, 16, 19 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Adams et al. (U.S. 2003/0229380). The rejections are traversed and reconsideration is respectfully requested.

As noted above, applicant has amended claims 1 and 11 herein to recite a device and method for delivering parasympathetic stimulation of the heart in conjunction with multi-site ventricular pacing, wherein the multi-site ventricular pacing is delivered in accordance with a demand pacing mode that prevents slowing of the heart rate due to the parasympathetic stimulation. For the reasons set forth below, applicant does believes that the recitations of claims 1 and 11, as well as the claims depending therefrom, are neither taught nor rendered obvious by the prior art of record.

Regarding the rejections under sections 102 and 103 based upon Adams et. al, the Adams et. al reference describes a device configured to deliver parasympathetic stimulation but does not describe a device that also delivers multi-site ventricular pacing in a manner that prevents the slowing of the heart rate by the parasympathetic stimulation. Furthermore, as the reference discusses delivering parasympathetic stimulation only for the express purpose of slowing the heart rate, applicant believes that Adams et. al actually teaches away from the method and device recited by claims 1 and 11. Regarding the assertions made in the office action with respect to the dependent claims, applicant finds no teaching in Adams et. al for a device configured to measure cardiac output, for controlling the delivery of parasympathetic stimulation in accordance with measured cardiac output, for controlling the delivery of parasympathetic stimulation in accordance with exertion level as reflected by measured activity level or minute ventilation, or for controlling the delivery of parasympathetic stimulation in accordance with a function of both exertion level and cardiac output.

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Regarding the rejections under section 102(e) based upon Casavant et al., that reference appears to only describe a device configured to deliver phrenic nerve stimulation in order to control respiration. Applicant finds no discussion of a device configured for delivering parasympathetic stimulation in conjunction with multi-site ventricular pacing where the multisite ventricular pacing is delivered in a manner that prevents the slowing of the heart rate due to the parasympathetic stimulation. Applicant can find nothing in paragraphs 35, 36, 60, and 71 or in Figs. 3-5 of Casavant et al. as cited in the office action that either teach or render obvious any of the recitations of claims 1-20.

Regarding the rejections under section 102(e) based upon the Shafer et al. reference, that reference appears to have a filing date of December 16, 2003 which is after the filing date of the present application. The Shafer et al. reference is therefore not prior art under section 102(e).

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (847) 432-7302 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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September 4, 2007

J. Kevin Parker

Reg. No. 33,024

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, 7.O. Box 1450, Alexandria, VA 22313-1450 on day of September 2007.

Signature

Name